K082689

MAR 2 0 2009

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510(k) Summary

for

Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP, 10 mL Ampule

1. DATE PREPARED

March 16, 2009

2. SPONSOR INFORMATION

A. NAME, ADDRESS AND TELEPHONE/FACSIMILE NUMBER

Spectra Medical Devices, Inc.
260 F & H Fordham Road
Wilmington, MA 01887

Contact Person:

Mr. Agustin Turriza

(978) 657-0889 x 225 (telephone)
(978) 657-4339 (facsimile)

aturriza@spectramedical.com

B. OUTSIDE REGULATORY COUNSEL

Foley & Lardner LLP
3000 K St., NW
Suite 500
Washington, DC 20007

Contact Person: David L. Rosen, B.S. Pharm., J.D.

(202) 672-5430 (telephone)
(202) 672-5399 (facsimile)
drosen@foley.com

3. DEVICE NAME

Proprietary Name:	Sodium Chloride Injection, 0.9%, USP 10 mL Ampule
Common/Usual Name:	Sodium Chloride Injection, 0.9%, USP 10 mL Ampule
Classification Names and numbers:	Saline, Vascular Access Flush Class II, General Hospital, NGT.

4. DEVICE DESCRIPTION AND INTENDED USE

Spectra Medical's, Sodium Chloride Injection, 0.9%, USP, 10 mL Ampule

Indications for Use:

The device is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. **Not to be used for any other purposes.**

5. PREDICATE DEVICE

a. K023740 - Syrex Pre-filled Syringe with 0.9% Sodium Chloride

b. Substantial Equivalence Comparison

Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP, 10 mL Ampule is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. Spectra Medical's Sodium

Chloride Injection, 0.9%, USP, 10 mL Ampule is identical to the predicate device. The difference is that the Spectra medical product is in a 10 mL ampule whereas the predicate device is in a syringe.

6. PERFORMANCE CHARACTERISTIC SUMMARY

There has been no change to the performance characteristics of the device system.

7. TECHNOLOGICAL CHARACTERISTICS

There has been no change to the fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2009

Spectra Medical Devices, Incorporated
C/o Mr. David Rosen
Foley & Lardner LLP
Washington Harbour
3000 K Street, NW, Suite 500
Washington, DC 20007

Re: K082689
Trade/Device Name: Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP, 10ML Ampule
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: March 2, 2009
Received: March 3, 2009

Dear Mr. Rosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K082689

Device Name: Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP, 10mL Ampule

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 082689

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